IN THE UNITED STATES DISTRICT COURT
DISTRICT OF KANSAS

MENDELL F. BUTLER, Plaintiff, v. JOHNSON & JOHNSON, a foreign corporation; ORTHO-McNEIL-JANSSEN PHARMACEUTICAL, INC., a foreign corporation; and JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT, L.L.C., a foreign corporation, Defendants.	Civil Action No. 10-1088-MLB-DWB JURY TRIAL DEMANDED DESIGNATED PLACE OF TRIAL: WICHITA, KANSAS

COMPLAINT

Plaintiff MENDELL F. BUTLER, an adult individual, by and through his counsel, in support of his complaint against the above-captioned Defendants, alleges the following:

INTRODUCTION

1. This case involves the fluoroquinolone antibiotic, Levoflaxacin.

2. Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and sold Levofloxacin in the United States as Levaquin from 1997 through the present.

3. The F.D.A. approved Levaquin for the treatment of a variety of serious infections; however, Defendants market Levaquin as a first-line therapy for common bronchitis and sinusitis infections, for which a myriad of other, safer antibiotics are available.

HUTTON & HUTTON Law Firm, L.L.C.

Tallgrass Exec. Park
8100 E. 22nd St. N.
Building 1200
Wichita, Kansas
67226-2312

Mailing Address:
P.O. Box 638
Wichita, Kansas
67201-0638

316.688.1166
316.686.1077 (*fax*)
www.huttonlaw.com

4. Compared to other fluoroquinolone antibiotic drugs, Levaquin causes a higher incidence of tendon injuries, including tendon rupture, especially in persons over 60 years of age and/or who are on corticosteroid therapy, none of which Defendants adequately disclosed to Plaintiff and his physicians.

5. Levaquin-induced tendon injury involves the degradation of the tendon tissue, leading to severe and permanent injuries.

6. Plaintiff suffered severe and debilitating tendon injuries after his use of Levaquin.

7. Plaintiff asserts claims against Defendants for strict product liability for manufacturing and/or design defect and failure to warn; negligence; breach of express and implied warranties for the design, manufacture, production, testing, study, inspection, labeling, marketing, advertising, sales, promotion, and distribution of Levaquin; violation of consumer protection laws; fraud; and unjust enrichment.

JURISDICTION

8. This Court has jurisdiction over this action pursuant to 28 U.S.C. §1332, because the amount in controversy exceeds Seventy-Five Thousand Dollars ($75,000.00), exclusive of interest and costs, and because there is complete diversity of citizenship between the Plaintiff and Defendants.

9. Venue is proper in this judicial district pursuant to 28 U.S.C. §1391 because Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and sold the prescription drug Levaquin within this judicial district, and because Defendants are subject to personal jurisdiction within the State of Kansas.

HUTTON
& HUTTON
Law Firm, L.L.C.

Tallgrass Exec. Park
8100 E. 22nd St. N.
Building 1200
Wichita, Kansas
67226-2312

Mailing Address:
P.O. Box 638
Wichita, Kansas
67201-0638

316.688.1166
316.686.1077 (*fax*)
www.huttonlaw.com

PARTIES

10. Plaintiff Mendell F. Butler is an adult citizen and resident of Wichita, Kansas.

11. Defendant JOHNSON & JOHNSON is a New Jersey corporation with its principal place of business in New Jersey. Its resident agent is Steven M. Rosenberg, at One Johnson & Johnson Plaza, New Brunswick, NJ 08933.

12. Defendant ORTHO-McNEIL-JANSSEN PHARMACEUTICALS, INC. ("OMJPI"), came into existence when Ortho-McNeil Pharmaceuticals, Inc., transferred its assets and liabilities to Janssen Pharmaceutica, Inc., in December 2007. A wholly-owned subsidiary of Defendant Johnson & Johnson, Defendant OMJPI is a Pennsylvania corporation with its principal place of business in New Jersey. Its resident agent is The Corporation Trust Company, Inc., 515 South Kansas Avenue, Topeka, Kansas 66603.

13. Defendant JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH & DEVELOPMENT ("JJPRD") is a New Jersey corporation with its principal place of business in New Jersey. Defendant JJPRD is a wholly-owned subsidiary of Defendant Johnson & Johnson and was known formerly as R.W. Johnson Pharmaceutical Research Institute. Its resident agent is Johnson & Johnson, One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

14. At all times relevant, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and sold the prescription drug Levaquin in interstate commerce and throughout the State of Kansas. At all times relevant, Defendants conducted business in the State of Kansas.

GENERAL FACTUAL ALLEGATIONS

15. Levaquin, Defendants' brand name for the antibiotic levofloxacin, is a broad-spectrum, synthetic antibacterial agent approved for use in the treatment of a variety of upper respiratory

HUTTON & HUTTON
Law Firm, L.L.C.

Tallgrass Exec. Park
8100 E. 22nd St. N.
Building 1200
Wichita, Kansas
67226-2312

Mailing Address:
P.O. Box 638
Wichita, Kansas
67201-0638

316.688.1166
316.686.1077 (*fax*)
www.huttonlaw.com

infections, urinary tract infections, prostatitis, and other bacterial infections. Defendants first introduced Levaquin into the U.S. market in 1997.

16. Levaquin is in a class of antibiotics known as fluoroquinolones. The original quinolone antibiotics were developed in the early 1960's and soon revealed themselves as highly effective against common gram-negative bacteria. Resistance rapidly developed. Twenty years later, in the early 1980's, fluorinated derivatives of the quinolones emerged, revealing a broader, more potent antibiotic, effective against many different types of infections. These so-called "second generation" fluoroquinolones included norfloxacin (Noroxin), ciprofloxacin (Cipro), ofloxacin (Floxin), and perfloxacin (never marketed in the U.S.).

17. Although considered highly effective at killing certain bacteria, fluoroquinolones have long been associated with serious side effects. Indeed, many fluoroquinolones have been removed from the market due to intolerable adverse events. For example, Omniflox (temafloxacin) was removed from the market in 1992 because of low blood sugar, kidney failure, and a certain rare form of anemia; Raxar and Zagam were removed due to QT-interval prolongation, among other things; Trovan was removed from the market due to severe liver toxicity; and most recently, Tequin was removed from the market in 2006 amid reports of severe blood sugar reactions, such as hyperglycemia and hypoglycemia.

18. In sum, though fluoroquinolones may share certain pharmacological properties, their safety profiles can differ immensely.

A. OFLOXACIN – THE FIRST GENERATION OF LEVAQUIN

19. To understand the pharmacological properties of Levaquin, one need look no further than to Levaquin's older brother, ofloxacin (Floxin), another Defendant-manufactured and -distributed drug.

HUTTON
& HUTTON
Law Firm, L.L.C.

Tallgrass Exec. Park
8100 E. 22nd St. N.
Building 1200
Wichita, Kansas
67226-2312

Mailing Address:
P.O. Box 638
Wichita, Kansas
67201-0638

316.688.1166
316.686.1077 (*fax*)
www.huttonlaw.com

20. Daiichi, a Japanese company, holds the patent on and developed both Floxin and Levaquin. Daiichi assigned the patents to Defendants and gave Defendants an exclusive license to manufacture and market both its fluoroquinolone compounds in the United States in return for royalty fees. Daiichi licenses levofloxacin to Aventis for manufacture and market in Europe. To date, Levaquin remains one of Daiichi's best selling pharmaceuticals.

21. Daiichi created an international database to track adverse events involving levofloxacin. This database ensured that Defendants could not ignore the post-market experience of levofloxacin in other countries.

22. Ofloxacin emerged onto the Japanese market in September 1985. Defendants introduced ofloxacin, under the brand name Floxin, in the United States six years later, in 1991.

23. Even before marketing ofloxacin in Japan, Daiichi began researching products that could be its successor. Daiichi wanted to develop a newer fluoroquinolone in order to be more competitive with Cipro and the other fluoroquinolones by developing a drug with the same or better characteristics of ofloxacin for oral or injected use.

24. After exploring and synthesizing many ofloxacin derivatives, Daiichi isolated what is now known as levofloxacin. Levofloxacin is a purified version of one optically-active form of ofloxacin, more specifically, the L-isomer.

25. Accordingly, ofloxacin and Levaquin are pharmacologically very similar – in fact, so similar that Defendants allege in their New Drug Application for Levaquin that the safety profile of Levaquin should mirror that of ofloxacin.

26. Unfortunately, while Levaquin closely followed the safety profile of ofloxacin, Levaquin was worse with respect to certain side effects, including tendon toxicity.

HUTTON
& HUTTON
Law Firm, L.L.C.

Tallgrass Exec. Park
8100 E. 22nd St. N.
Building 1200
Wichita, Kansas
67226-2312

Mailing Address:
P.O. Box 638
Wichita, Kansas
67201-0638

316.688.1166
316.686.1077 (*fax*)
www.huttonlaw.com

B. EPIDEMIOLOGY OF FLUOROQUINOLONE TENDON TOXICITY – OFLOXACIN IS MORE TENOTOXIC THAN THE REST, AND THE ELDERLY AND USERS OF CORTICOSTEROIDS ARE AT A HEIGHTENED RISK

27. The first report of tendonitis as a side effect of fluoroquinolones came in 1983. The first case of Achilles tendon rupture was reported in 1991 in conjunction with pefloxacin – a fluoroquinolone that the FDA never approved for U.S. use, in part due to its teno-toxicity. Potentially due to pefloxacin's early use in France, by 1994, Dr. Pierfitte *et al*. identified over 100 French patients with fluoroquinolone tendon disorders (mostly from pefloxacin), and was able to observe that tendon injury occurred more frequently in patients over 60, and especially in those who had received steroid therapy.

28. Although the Achilles tendon was affected the most, and bilaterally in many cases, Dr. Pierfitte reported that other tendons could be implicated as well. Accordingly, the French regulatory body was one of the first to notify physicians and their patients about the risk of fluoroquinolones-induced tendon injury. Additionally, as a likely result of Dr. Pierfitte's published observations, perfloxacin use became severely restricted by 1995.

29. Once pefloxacin became restricted, Defendants' first-generation ofloxacin emerged as the most tenotoxic fluoroquinolone on the market.

30. In 1995 the British Journal of Clinical Pharmacology published one of the first reports regarding the tendon toxicity of ofloxacin. *See* Wilton, L.V., Pearce, G.L., Mann, R.D., A comparison of ciprofloxacin, norfloxacin, ofloxacin, azithromycin and cefixime examined by observational cohort studies. Br J Clin Parmacol 1996; 41:277-284.

31. In the Wilton report, an analysis of prescription event monitoring data in the United Kingdom (where pefloxacin was not approved for market) revealed that ofloxacin was more tenotoxic than the other fluoroquinolones examined.

HUTTON & HUTTON Law Firm, L.L.C.

Tallgrass Exec. Park
8100 E. 22nd St. N.
Building 1200
Wichita, Kansas
67226-2312

Mailing Address:
P.O. Box 638
Wichita, Kansas
67201-0638

316.688.1166
316.686.1077 (*fax*)
www.huttonlaw.com

32. The United Kingdom's Regulatory Authority issued a bulletin, published in July 1995, stating that it had received 21 reports of tendon damage associated with fluoroquinolone antibiotics. The Authority reported that "elderly patients and those treated concurrently with corticosteroid are at particular risk."

33. Defendants submitted their New Drug Application regarding Levaquin to the FDA in 1995. Though they indicate that tendon disorders are associated with fluoroquinolone use, Defendants failed to report that ofloxacin was more tendon toxic than other currently-marketed fluoroquinolones and failed to report that the tendon toxicity was exacerbated in the elderly, and especially in those taking corticosteroids.

34. Pharmaco-epidemiologists and researchers at the Department of Epidemiology and Biostatistics and Internal Medicine at Erasmus Medical Center in Rotterdam published in 1999 the first epidemiological study to evaluate the relative risk of fluoroquinolone-induced tendonitis. Van der Linden PD, Van de Lie J, Nab KW, Knok A, Stricker B H Ch, Achilles tendonitis associated with fluoroquinolones. Br J Clin Pharmacol 1999; 48: 433-437.

35. Data analyzed in this retrospective cohort study from 41 general practices in the Netherlands from 1995-1996 revealed that ofloxacin had the strongest association with Achilles tendonitis. The adjusted relative risk of tendonitis to fluoroquinolones was 3.7, while Achilles tendonitis associated with ofloxacin had a relative risk of 10.1. Upon information and belief, Defendants knew of this study and had an obligation to inform the FDA of this study by supplementing their New Drug Application.

36. A second epidemiological study published in 2002 by Van der Linden, *et al.*, analyzed data from the IMS Health database in the United Kingdom, which contained general practice medical records on a source population of 1-2 million inhabitants. Van der Linden, PD, Sturdenboom MCJM,

HUTTON
& HUTTON
Law Firm, L.L.C.

Tallgrass Exec. Park
8100 E. 22nd St. N.
Building 1200
Wichita, Kansas
67226-2312

Mailing Address:
P.O. Box 638
Wichita, Kansas
67201-0638

316.688.1166
316.686.1077 (*fax*)
www.huttonlaw.com

Herings RMC, Leufkens HGM, Stricker BH Ch, Fluoroquinolones and risk of Achilles tendon disorders: case control study. BMJ 2002; 324: 1306-07.

37. In this nested case control study, the authors again found that ofloxacin was associated with an eleven-fold increase in tendon disorders. More specifically, the authors found that the relative risk of Achilles tendon disorders following current use of fluoroquinolones was 1.9, but in patients over 60 years of age, the relative risk was 3.2. However, in the elderly, the relative risk was 11.5 for current use of ofloxacin, compared to 2.3 and 1.8 for ciprofloxacin and norfloxacin, respectively. In patients of 60 years and older, concurrent use of corticosteroids and fluoroquinolones increased the risk to 6.2. Upon information and belief, Defendants knew of this study and had an obligation to inform the FDA of this study by supplementing their New Drug Application.

38. Soon thereafter, in 2003, Dr. Van der Linden published his final epidemiological study, a larger population-based case control study that analyzed cases of Achilles tendon rupture and fluoroquinolone use from 1988 to 1998. Stunningly, his report concludes that the relative risk of a tendon injury in patients over 60 years old taking ofloxacin was 27.7 compared to ciprofloxacin's 3.4. He also found that use of corticosteroids nearly doubled the risk for tendon injury for patients over 60 years old.

39. Even Daiichi, the inventor of ofloxacin and Levaquin, published a 1997 rat study that admitted that Levaquin and ofloxacin were the most toxic to tendons of all the fluoroquinolones marketed in the United States. The study was designed not only to understand better the pathophysiological mechanism of fluoroquinolone-induced tendon disorders, but also to compare the relative tendon toxicity of ten different fluoroquinolones.

40. Although the exact mechanism of how fluoroquinolones cause tendon injury is still under investigation, studies have suggested that fluoroquinolones can degrade tendon cells by causing

HUTTON & HUTTON Law Firm, L.L.C.

Tallgrass Exec. Park
8100 E. 22nd St. N.
Building 1200
Wichita, Kansas
67226-2312

Mailing Address:
P.O. Box 638
Wichita, Kansas
67201-0638

316.688.1166
316.686.1077 (*fax*)
www.huttonlaw.com

apoptosis, or a programmable cell death, and, therefore make tendons lose their integrity and easily tear and/or rupture.

41. The outcome of Achilles tendon ruptures in persons over 60 – the population most affected by this adverse reaction – is not favorable. Treatment may include a corticosteroid to decrease inflammation – ironically, the very drug that, when combined with a fluoroquinolone, can dramatically increase the risk of a tendon rupture. In the event of a tendon rupture, the leg often is immobilized through a boot or other casting for anywhere between six weeks to six months, and physical therapy occurs thereafter. Surgery seldom is the recommended treatment in the elderly population due to poor recovery rates. However, even with immobilization for long period of time and physical therapy, the Achilles tendons in the elderly rarely fully recover.

C. THE FIRST U.S. TENDON WARNING

42. According to the U.S. consumer watchdog organization, Public Citizen, by 1996 there were over 130 reports of tendon injury from around the world over a ten year period and 52 reports of tendon injury in the United States associated with fluoroquinolone use.

43. As there was no mention of any fluoroquinlone-induced tendon injury on the label, Public Citizen petitioned the FDA in 1995, based on a number of adverse event reports world wide, to require that manufacturers of fluoroquinolones revise their product label to alert physicians of this unusual adverse event.

44. The FDA responded by requiring the warning on all fluoroquinolone labels:

> Ruptures of the shoulder, hand, and Achilles tendons that required surgical repair or resulted in prolonged disability have been reported with [the specific drug name]. [The specific drug name] should be discontinued if the patient experiences pain, inflammation, or rupture of a tendon. Patients should rest and refrain from exercise until the diagnosis of tendonitis or tendon rupture has been confidently excluded. Tendon rupture can occur at any time during or after therapy with [the specific drug name].

HUTTON & HUTTON Law Firm, L.L.C.

Tallgrass Exec. Park
8100 E. 22nd St. N.
Building 1200
Wichita, Kansas
67226-2312

Mailing Address:
P.O. Box 638
Wichita, Kansas
67201-0638

316.688.1166
316.686.1077 (*fax*)
www.huttonlaw.com

45. By 1997, U.S. manufactures of fluoroquinolones had modified their label. However, the label was buried in a long list of potential adverse reactions; it was not highlighted in any way, such as with bold lettering, or even a heading titled "tendon injury." Moreover, no mention was made of the fact that age and corticosteroid use tripled the risk of tendon injury. Defendants disseminated no letters to physicians and did not highlight this unusual effect when promoting Levaquin to doctors.

D. LEVAQUIN'S EARLY POST-MARKET EXPERIENCE

46. Defendants first introduced Levaquin in Japan in 1993 and into the United States in 1997.

47. Before Defendants launched Levaquin in the United States, Defendants knew or should have known that:

a. Levaquin would be as toxic as ofloxacin;

b. Ofloxacin was revealing itself as one of the most tenotoxic fluoroquinolones on the market; and

c. The elderly, and especially those using corticosteroids, were at least three times as likely to suffer a tendon injury

48. Despite this unique knowledge, Defendants chose to use the same label that the FDA required on all other fluoroquinolones. Accordingly in 1997, most U.S. physicians did not understand fluoroquinolone tendon toxicity, and were completely ignorant of the elderly's exceptional vulnerability to this antibiotic, especially those dependent on corticosteroids.

49. A look at Defendants' sales material could explain why: the very group to which that Levaquin was most was the very market that Defendants sought – the elderly, especially those with upper respiratory infections who were likely to be chronic corticosteroid users.

HUTTON
& HUTTON
Law Firm, L.L.C.

Tallgrass Exec. Park
8100 E. 22nd St. N.
Building 1200
Wichita, Kansas
67226-2312

Mailing Address:
P.O. Box 638
Wichita, Kansas
67201-0638

316.688.1166
316.686.1077 (*fax*)
www.huttonlaw.com

50. More disturbing, Defendants promoted Levaquin has having an excellent safety, but failed to disclose the risks of tendon injury.

51. Defendants capitalized on Levaquin's early introduction into Japan and other countries by using pre-U.S. prescription sales data to assert that Levaquin had been prescribed frequently with few adverse events.

52. For example, one such advertisement boasted that Levaquin had "An Outstanding Record of Safety" as "[o]ver 63,000,000 patients worldwide" had taken the drug and only diarrhea and nausea had shown up as adverse effects, albeit rarely.

53. Cleverly, the promotional literature only reported on adverse events in U.S. clinical trials where only a very small sampling of patients took their drug, and where many adverse events do not necessarily reveal themselves. So, Defendants claimed "proven performance" on the 63,000,000 million people who had used Levaquin outside the United States, but chose not to disclose the adverse events that were being reported on this same population.

54. As Levaquin gained traction, its "Achilles heel" of heightened toxicity revealed itself.

55. Levaquin enjoyed immediate popularity in the Italian market. Introduced to Italy in 1998, Levaquin became Italy's best selling fluoroquinolone, surpassing Cipro, the major market leader, in just three years. Curiously, ofloxacin, Defendants' previous fluoroquinolone, had the lowest market share, which was consistent with Daiichi's plan to "cannibalize" ofloxacion in favor of Levaquin.

56. One of the first comparative studies that included post market experience with Levaquin was from Italy. The authors analyzed Italian adverse event data from 1999 to 2001 to help determine the relative toxicity of each marketed fluoroquinolone antibiotic.

57. The Italian study was published in 2003 and revealed that:

HUTTON & HUTTON Law Firm, L.L.C.

Tallgrass Exec. Park
8100 E. 22nd St. N.
Building 1200
Wichita, Kansas
67226-2312

Mailing Address:
P.O. Box 638
Wichita, Kansas
67201-0638

316.688.1166
316.686.1077 (*fax*)
www.huttonlaw.com

a. the most frequently reported serious reaction to fluoroquinolones were tendon disorders;

b. levofloxacin was the fluoroquinolone with the highest tendonitis reporting rate; and

c. levofloxacin ranked first for tendonitis reports during the same period in the World Health Organization's adverse event database, with 522 reports of levofloxacin-induced tendon disorders and ruptures.

58. Not surprisingly, in March 2002, the Italian Health Ministry issued a "Dear Doctor" letter to inform physicians of the risk of Levaquin tendon rupture.

59. France also reported a particularly large amount of tendon disorder soon after Levaquin was first marketed to that country in September 2000. By June 2001, in just nine months, 333 adverse reactions had been reported, with tendon disorder being the most frequently reported adverse event. Again, the adverse event data supported the epidemiological evidence finding that tendon injuries were more prominent in the elderly, especially when there had been co-administration of corticosteroids.

60. France's regulatory authority published a "Dear Doctor" letter to highlight this information in 2002.

61. Similarly, the Belgian regulatory authority received 161 reports of Levaquin-induced tendon injury, including 68 reports of tendon rupture, in the first two years of Levaquin's introduction to Belgium. Again, the average age of patients with levofloxacin-associated tendinopathy was 69 years old and about half were receiving concomitant corticosteroid treatment. As with other adverse event data, the tendon injuries were reported to occur soon after the patient ingested Levaquin. Belgium also noted, similar to Italy, that the number of tendon disorders associated with levofloxacin

HUTTON
& HUTTON
Law Firm, L.L.C.

Tallgrass Exec. Park
8100 E. 22nd St. N.
Building 1200
Wichita, Kansas
67226-2312

Mailing Address:
P.O. Box 638
Wichita, Kansas
67201-0638

316.688.1166
316.686.1077 (*fax*)
www.huttonlaw.com

was much higher than that of the other quinolones. Not surprisingly, ofloxacin had the second highest reports for tendon injury.

62. Recognizing that the number of tendon effects from Levaquin were far more frequent than any other fluoroquinolones that had all been on the market over the past ten years, the Belgium regulatory authority also disseminated a "Dear Doctor" letter in 2002 highlighting their concerns about levofloxacin's toxicity and suggesting that levofloxacin is only justified for the treatment of community-acquired pneumonia in patients who are allergic to beta-lactams. The agency stressed that the elderly and people who used corticosteroids were particularly at risk and encouraged doctors to watch for tendon injury should they prescribe levofloxacin.

63. After nearly five years on the market in the United States, and following the post-marketing data out of Europe, Defendants finally decided to update their tendon warning.

E. LEVAQUIN'S SECOND TENDON WARNING

64. The pre-2002 Levaquin label bore the required tendon warning from its market launch in 1997. It was the last of the warnings listed, with no header or any other identification to alert a practitioner to this unusual side effect. The warning was behind gastrointestinal affects, hypersensitivity reactions, and even the rare event of anaphylactic shock.

65. In 2002, Defendants embedded the following in the existing tendon warning: "Post-marketing surveillance reports indicate that this risk may be increased in patients receiving concomitant corticosteroids, especially in the elderly."

66. Through an international database that Daiichi managed, Defendants had access to the post-market surveillance data all over the world, and specifically France, Belgium, Italy, and the United Kingdom.

HUTTON & HUTTON Law Firm, L.L.C.

Tallgrass Exec. Park
8100 E. 22nd St. N.
Building 1200
Wichita, Kansas
67226-2312

Mailing Address:
P.O. Box 638
Wichita, Kansas
67201-0638

316.688.1166
316.686.1077 (*fax*)
www.huttonlaw.com

67. By 2002, the adverse event data in all those countries consistently and unequivocally revealed that the risk of tendon injury was nearly triple for people over 60 as compared to people under 60. Additionally, Defendants had knowledge of at least one epidemiological study confirming the age effects of fluoroquinolone use. All data pointed to the fact that Levaquin was more tendon toxic than all other fluoroquinolones.

68. Despite a wealth of information, Defendants chose not to warn their target patient population - the elderly - with their 2002 warning. Instead, they muted their additional tendon warning by flipping the confounders. Rather than warn that the risk of tendon risk was increased (tripled) in the elderly, the warning stated that the risk was possibly increased in those using corticosteroids. According to Defendants' warning, any elderly person not on corticosteroids, therefore, had no additional risk of a tendon injury, and the fact that the warning was so equivocal regarding corticosteroids diffused any possible effect of warning physicians of the effect of age on the frequency and severity of this debilitating injury.

69. Nor did Defendants make any effort to highlight this new information to its prescribing doctors - Defendants did not send any "Dear Doctor" letters regarding the 2002 label change to any healthcare practitioners, as had been done in Italy, Belgium, and France.

70. Accordingly, despite the 2002 label change, Levaquin prescriptions only increased, and tendon injuries mounted.

F. DEFENDANTS THWART EFFORTS TO HIGHLIGHT LEVAQUIN'S INCREASED RISK OF TENDON INJURY

71. Alarmed by the early post market experience with Levaquin, France, Belgium, Italy, the United Kingdom, and other European countries convened before the European Agency for the

HUTTON & HUTTON Law Firm, L.L.C.

Tallgrass Exec. Park
8100 E. 22nd St. N.
Building 1200
Wichita, Kansas
67226-2312

Mailing Address:
P.O. Box 638
Wichita, Kansas
67201-0638

316.688.1166
316.686.1077 (*fax*)
www.huttonlaw.com

Evaluation of Medicinal Products (EMEA) as early as September 2001 to discuss a heightened warning for levofloxacin.

72. The EMEA proposal was that levofloxacin would be singled out as the most tendon toxic of the fluoroquinolones with a warning that stated that levofloxacin (marketed under the brand name Tavanic) was associated with a greater frequency of tendinopathy and tendon rupture than other fluoroquinolones.

73. Aventis Pharmaceutical was the manufacturer and distributor of levofloxacin in Europe.

74. Under increasing pressure to agree to the proposed changes to the warning label, Aventis conducted two epidemiological studies in Europe regarding the relative tendon toxicity of levofloxacin. The first study used the United Kingdom's General Practitioners Research Database of medical records from 1997 through 2001, and the second used Germany's Mediplus database of medical records from 1998 to 2001.

75. Before releasing the results of the two epidemiology studies to the European regulatory authorities, and ostensibly because of the results of the studies, Aventis contracted with Defendants, specifically Johnson & Johnson Pharmaceutical Research & Development, to fund and co-author a study in the United States on tendon rupture and fluoroquinolones.

76. Advocating that the U.S. Study would be the largest epidemiological study to date and therefore provide the most definitive evidence of the relative risk of levofloxacin and tendon injury, and that the European studies to date were too small from which to base a label change, Aventis convinced the European regulatory authorities to forestall the proposed warning change until the preliminary data from the U.S. study was released.

HUTTON
& HUTTON
Law Firm, L.L.C.

Tallgrass Exec. Park
8100 E. 22nd St. N.
Building 1200
Wichita, Kansas
67226-2312

Mailing Address:
P.O. Box 638
Wichita, Kansas
67201-0638

316.688.1166
316.686.1077 (*fax*)
www.huttonlaw.com

77. In or around April 2002, Aventis submitted the results of their two European epidemiological studies to the United Kingdom's regulatory authority, the Medicines and Healthcare Products Regulatory Agency (MHRA).

78. The epidemiology studies that Aventis conducted in Europe concluded that levofloxacin was associated with a higher rate of tendon injury than all the other fluoroquinolones compared. Ofloxacin, the fluoroquinolone indicted in early epidemiological studies as the most teno-toxic, came in second.

79. An assessor at the MHRA concluded that the two epidemiological studies had findings "supporting a signal generated by spontaneous reporting with respect to an increased risk of tendinopathy with levofloxacin compared to other fluoroquinolones."

80. Moreover, the assessor remarked that "the finding that ofloxacin (the racemate) is associated with an intermediate level of risk makes pharmacological sense, suggesting that the L- rather than the D-isomer of ofloxacin is likely to be responsible for tendon toxicity....given the consistency and plausibility of the findings, a real difference is the most likely explanation."

81. By the time Aventis released the results of their epidemiological studies, the preliminary results of the U.S. study was reportedly only six months away. Accordingly, the European regulatory authorities agreed to wait before forcing a label change.

82. Defendant Johnson & Johnson Pharmaceutical Research & Development funded and co-authored the U.S. epidemiological study.

83. Unlike the healthcare databases in Europe that contain computerized medical records, Johnson & Johnson PRD used data from the Ingenix Research database, which consisted of U.S. health insurance claims data from 1997 to 2001. The study analyzed only Achilles tendon ruptures

HUTTON
& HUTTON
Law Firm, L.L.C.

Tallgrass Exec. Park
8100 E. 22nd St. N.
Building 1200
Wichita, Kansas
67226-2312

Mailing Address:
P.O. Box 638
Wichita, Kansas
67201-0638

316.688.1166
316.686.1077 (*fax*)
www.huttonlaw.com

and sought to examine whether fluoroquinolone exposure was a risk factor for this injury. It did not assess the relative risk of Levaquin tendon toxicity, as the United Kingdom had requested.

84. Under the guise of data validation, Defendant Johnson & Johnson PRD created an algorithm that conveniently excluded nearly 70 percent of health claims for elderly persons who suffered Achilles tendon rupture.

85. The algorithm used CPT procedure codes that only related to surgical repair, which thereby, excluded all those Achilles tendon rupture cases where the patient was casted or booted, as is the case in the elderly population.

86. By manipulating the data, Defendant Johnson & Johnson PRD was able to exclude the very group that was prone to tendon rupture.

87. Not surprisingly, the results of the U.S. epidemiological study – the study upon which hinged regulatory action in Europe with ramifications to the U.S. market – revealed for the first time that there was no increased risk of Achilles tendon rupture associated with any fluoroquinolone use. Neither the confounders of age nor corticosteroid use altered these findings.

88. Indeed, when one includes the data that was excluded by the algorithm, the result becomes consistent with the approximately eight other epidemiological studies performed on the topic. See Seeger *et al.* Achilles Tendon Rupture and its Associations with Fluoroquinolone Antibiotics and Other Potential Risk Factors in A Managed Care Population, Pharmacoepidemiology and Drug Safety 2006; 15: 784-792 ("There was a stronger association with fluoroquinolone antibiotic exposure among these "ruled-out" cases of ATR . . than among the decision rule confirmed cases. This association was stronger with exposure close to the date of the rupture and was more pronounced among the elderly.")

HUTTON
& HUTTON
Law Firm, L.L.C.

Tallgrass Exec. Park
8100 E. 22nd St. N.
Building 1200
Wichita, Kansas
67226-2312

Mailing Address:
P.O. Box 638
Wichita, Kansas
67201-0638

316.688.1166
316.686.1077 (*fax*)
www.huttonlaw.com

89. As a result of Defendants' misrepresentation in the U.S. study, the MHRA and the other European regulatory agencies chose note to revise the levofloxacin label as they had previously recommended.

G. DEFENDANTS DOWNPLAY THE RISK OF LEVAQUIN TO PHYSICIANS

90. Consistent with their plan to downplay Levaquin's known risk of tendon injury, Defendants made no attempts to educate physicians in the United States about this unusual adverse event. Although "Dear Doctor" letters had been widely disseminated throughout Europe advising of Levaquin's tendon toxicity and the vulnerability of this adverse event to the elderly, Defendants did not so advise the U.S. physicians.

91. Defendants' plan was to hide behind the class warning and blame any tendon injuries reported on the general pharmacological properties of a fluoroquinolone antibiotic rather than on the L-isomer of the ofloxacin compound as the Aventis studies suggested.

92. The promotional material that Defendants, and specifically, Ortho-McNeil, designed and distributed to physicians, consistently omits the risk of tendon injury.

93. Accordingly, physicians continued to prescribe Levaquin, believing it to have the same safety profile as Cipro and unaware of the heightened affect of Levaquin on the elderly population.

H. AN EXPLOSION OF TENDON INJURIES RESULTS IN THE THIRD LABEL CHANGE

94. A review of the events in the FDA Adverse Event database from 1997 through 2005, for Levaquin alone, showed 1,044 reports of tendon injuries, with 282 reports of tendon rupture. This six year figure for tendon affects associated with Levaquin far surpassed the ten year history of tendon affects from 1985 through 1995 associated with all pre-Levaquin fluoroquinolones.

HUTTON & HUTTON
Law Firm, L.L.C.

Tallgrass Exec. Park
8100 E. 22nd St. N.
Building 1200
Wichita, Kansas
67226-2312

Mailing Address:
P.O. Box 638
Wichita, Kansas
67201-0638

316.688.1166
316.686.1077 (*fax*)
www.huttonlaw.com

95. After Cipro went generic in 2003, Levaquin became the number one prescribed fluoroquinolone in the United States. And when Zithromax, a highly popular macrolide antibiotic, went generic after its patent expired in 2005, Levaquin became the number one prescribed antibiotic in the world in 2006.

96. Corresponding with Levaquin's increased popularity, the number of adverse events reported to the FDA reported soared. Reported in 2006 were143 tendon related injuries. In just the first quarter of 2007, 107 tendon related injuries were reported where Levaquin was the primary suspect.

97. The Illinois Attorney General noticed this Levaquin phenomenon. On May 18, 2005, the Attorney General submitted a petition to the FDA, requesting a black box warning on fluoroquinolones. The Attorney General suggested that the black box was necessary to highlight the seriousness of tendon injuries and that the risk is increased in the elderly and in patients on corticosteroids.

98. The Attorney General also requested that the manufacturer issue a "Dear Doctor" letter to inform the health care providers about this significant hazard to health, as the tenotoxic affects of fluoroquinolones were not well known to practicing physicians.

99. In the Petition, the Attorney General's office reviewed the literature and stated that tendon injuries were not a rare complication of fluoroquinolone use. The Petition complained that the current tendon warning was "buried in lists of potential side effects which are both less frequent and less severe."

100. One year later, the same consumer watchdog organization that petitioned the FDA in 1996 for a tendon warning, petitioned the FDA again saying the first tendon warning did not go far enough. Citing the alarming increase in reports of tendon injury, Public Citizen joined the Illinois

HUTTON
& HUTTON
Law Firm, L.L.C.

Tallgrass Exec. Park
8100 E. 22nd St. N.
Building 1200
Wichita, Kansas
67226-2312

Mailing Address:
P.O. Box 638
Wichita, Kansas
67201-0638

316.688.1166
316.686.1077 (*fax*)
www.huttonlaw.com

Attorney General's petition and urged that the FDA place a black box warning regarding the risk of tendonitis and tendon ruptures.

101. At the request of the FDA, in April 2007, the Levaquin label changed for a third time with regard to tendon injuries. The new label is not a black box, but it now states that indeed the elderly are at an increased risk of tendon injury, and unequivocally states that the risk is increased with concomitant use of corticosteroids, contrary to the results of Defendant's Ingenix study.

102. Upon information and belief, Defendants negotiated with the FDA and insisted in a class warning to thereby minimize the heightened risk of tendon injury with Levaquin.

103. The current class warning fails to alert physicians and prescribing health care providers that Levaquin is more toxic to the tendons than the other fluoroquinolones available in the U.S. market. Health care providers have no warning that Levaquin is much more tenotoxic than other drugs in the class and therefore will interpret the relative risk of a Levaquin-induced tendon injury inappropriately.

104. Defendants, upon information and belief, have not advised physicians of the 2007 label change and therefore, it is not known when physicians might receive this new information regarding the vulnerability of the elderly population to a Levaquin-induced injury.

105. Defendants continue to market Levaquin as a first line therapy for common bronchitis and sinusitis infections, and for which many other, safer, antibiotics are available.

HUTTON
& HUTTON
Law Firm, L.L.C.

Tallgrass Exec. Park
8100 E. 22nd St. N.
Building 1200
Wichita, Kansas
67226-2312

Mailing Address:
P.O. Box 638
Wichita, Kansas
67201-0638

316.688.1166
316.686.1077 (*fax*)
www.huttonlaw.com

SPECIFIC FACTUAL ALLEGATIONS

106. Mr. Mendell Butler was 79 years old in 2009 when his doctor prescribed and Mr. Butler consumed Levaquin to treat an upper respiratory infection. Shortly after completing his course of Levaquin, Mr. Butler suffered a left ruptured bicep tendon, severe and permanent injuries for which there is no repair and from which he never will recuperate fully. His left arm is very weak and always painful.

FIRST CAUSE OF ACTION
STRICT LIABILITY

107. Plaintiff incorporates here all prior paragraphs of this Complaint and further alleges:

108. Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and sold Levofloxacin, otherwise known as Levaquin, to medical professionals and their patients, knowing it that patients would ingest it for the treatment of infections.

109. Levaquin reached Plaintiff without substantial change in its condition and Plaintiff used it in a reasonable, foreseeable, and intended manner.

110. Levaquin was "defective" and "unreasonably dangerous" when it entered the stream of commerce and when Plaintiff received it, because it was dangerous to an extent beyond that which the ordinary consumer could contemplate. At no time did Plaintiff have reason to believe that Levaquin was in a condition not suitable for its proper and intended use among patients.

111. To his detriment, Plaintiff used Levaquin in the manner that Defendants intended, namely, for treatment of bacterial infections.

112. Plaintiff was not able to discover, nor could he have discovered through the exercise of reasonable care, the defective nature of Levaquin. Further, in no way could Plaintiff have known

HUTTON
& HUTTON
Law Firm, L.L.C.

Tallgrass Exec. Park
8100 E. 22nd St. N.
Building 1200
Wichita, Kansas
67226-2312

Mailing Address:
P.O. Box 638
Wichita, Kansas
67201-0638

316.688.1166
316.686.1077 (*fax*)
www.huttonlaw.com

that Defendants had tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and sold Levaquin in such a way as to increase the risk of harm or injury to the recipients of Levaquin.

113. Levaquin is defective in design because of its propensity to cause tendon ruptures and other serious tendon injuries.

114. Levaquin is unreasonably dangerous because Defendants sold it to Plaintiff without adequate warnings regarding, *inter alia*, the propensity of Levaquin to cause serious tendon injuries; the post-marketing experience with Levaquin; the increased risk of tendon injury in patients over the age of 60; the numbers of tendon-related averse events reported; and the probability of suffering an acute tendon injury when ingesting corticosteroids concomitantly with Levaquin or post-Levaquin use.

115. Defendants failed to develop and make available alternative products that were designed in a safe manner, even though such products were feasible and marketable at the time Defendants sold Levaquin to Plaintiff.

116. Defendants knew or should have known about the defective and dangerous nature of Levaquin. Despite this knowledge and information, Defendants failed to warn Plaintiff and his physicians adequately and sufficiently that Levaquin causes serous tendon injuries including, without limitation, tendon rupture.

117. As a direct and proximate result of Defendants' wrongful conduct, including Levaquin's defective and dangerous design and inadequate warnings, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, economic loss, and other damages including, but not limited to, cost of medical care, rehabilitation, and pain and suffering, for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

HUTTON
& HUTTON
Law Firm, L.L.C.

Tallgrass Exec. Park
8100 E. 22nd St. N.
Building 1200
Wichita, Kansas
67226-2312

Mailing Address:
P.O. Box 638
Wichita, Kansas
67201-0638

316.688.1166
316.686.1077 (*fax*)
www.huttonlaw.com

SECOND CAUSE OF ACTION
NEGLIGENCE

118. Plaintiff incorporates here all prior paragraphs of this Complaint and further alleges:

119. At all relevant times, Defendants had a duty to exercise reasonable care in the design, formulation, testing, promotion, sale, and distribution of Levaquin, including a duty to ensure that Levaquin did not pose a significantly increased risk of bodily injury to its users.

120. Defendants had a duty to exercise reasonable care in the advertising and sale of Levaquin, including a duty to warn Plaintiff and other consumers, of the dangers associated with the consumption of Levaquin that Defendants knew or should have known at the time of the sale of Levaquin to the Plaintiff.

121. Defendants failed to exercise reasonable care in the testing, study, research, design, formulation, manufacture, inspection, labeling, packaging, promotion, advertising, marketing, distribution, and sale of Levaquin because Defendants knew or should have known that Levaquin had a propensity to cause serious injury, including tendon rupture and other serious tendon injuries.

122 Defendants failed to exercise ordinary care in the labeling of Levaquin and failed to issue adequate pre-marketing or post-marketing warnings to prescribing doctors and the general public regarding the risk of serious injury, including, without limitation, tendon rupture.

123. Defendants knew or should have known that Plaintiff foreseeably could suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

124. Defendants breached their duty of reasonable care to Plaintiff by failing to exercise due care under the circumstances.

125. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the testing, study, research, design, formulation, manufacture,

HUTTON
& HUTTON
Law Firm, L.L.C.

Tallgrass Exec. Park
8100 E. 22nd St. N.
Building 1200
Wichita, Kansas
67226-2312

Mailing Address:
P.O. Box 638
Wichita, Kansas
67201-0638

316.688.1166
316.686.1077 (*fax*)
www.huttonlaw.com

inspection, labeling, packaging, promotion, advertising, marketing, distribution, and sale of Levaquin, Plaintiff ingested Levaquin and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, and pain and suffering, for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

THIRD CAUSE OF ACTION
BREACH OF IMPLIED WARRANTIES

126. Plaintiff incorporates here all prior paragraphs of this Complaint and further alleges:

127. Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and sold Levaquin.

128. At the time Defendants marketed, sold, and distributed Levaquin, Defendants knew of the use for which they intended Levaquin and impliedly warranted that Levaquin was merchantable, safe, and fit for its intended purpose: namely that Plaintiff could ingest Levaquin without the risk of serious injury.

129. Plaintiff, a foreseeable user of Levaquin, and Plaintiff's physician(s), reasonably relied upon Defendants' judgment and implied warranties in purchasing and consuming Levaquin as intended.

130. Levaquin was defective, unmerchantable, and unfit for ordinary use when sold, and subjected Plaintiff to severe and permanent injuries.

131. Defendants breached their implied warranties because Levaquin was and continues to be neither of merchantable quality nor safe for its intended use in that Levaquin has the propensity to cause tendon rupture, other debilitating tendon injuries, and bodily harm.

HUTTON
& HUTTON
Law Firm, L.L.C.

Tallgrass Exec. Park
8100 E. 22nd St. N.
Building 1200
Wichita, Kansas
67226-2312

Mailing Address:
P.O. Box 638
Wichita, Kansas
67201-0638

316.688.1166
316.686.1077 (*fax*)
www.huttonlaw.com

132. As a direct and proximate result of Defendants' breach of the implied warranties of merchantability and fitness for its intended purpose, Plaintiff ingested Levaquin and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, and pain and suffering, for which he is entitled to compensatory and equitable damages in an amount to be proven at trial.

FOURTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY

133. Plaintiff incorporates here all prior paragraphs of this Complaint and further alleges:

134. Defendants through their marketing program, promotional activities, product labeling, package inserts, and other written and verbal assurances expressly warranted to physicians and consumers, including Plaintiff and/or his physicians, that scientific study had shown Levaquin to be safe for its intended use.

135. Plaintiff, and/or his physicians, reasonably relied upon Defendants' express warranties in purchasing, consuming, and prescribing Levaquin.

136. Defendants breached their express warranties because Levaquin, as Defendants manufactured and sold it, does not conform to these express representations in that Levaquin has a propensity to cause tendon rupture, other serious tendon injuries, and bodily harm.

137. As a direct and proximate result of Defendants' breach of their express warranties, Plaintiff ingested Levaquin and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, and pain and suffering, for which he is entitled to compensatory and equitable damages in an amount to be proven at trial.

FIFTH CAUSE OF ACTION
FRAUD

138. Plaintiff incorporates here all prior paragraphs of this Complaint and further alleges:

HUTTON
& HUTTON
Law Firm, L.L.C.

Tallgrass Exec. Park
8100 E. 22nd St. N.
Building 1200
Wichita, Kansas
67226-2312

Mailing Address:
P.O. Box 638
Wichita, Kansas
67201-0638

316.688.1166
316.686.1077 (*fax*)
www.huttonlaw.com

139. Defendants were under a duty, and failed to discharge their duty, to exercise reasonable care to disclose to Plaintiff and his doctors the defective nature and risks that Levaquin can cause severe and permanent injuries, including, without limitation, tendon ruptures, of which they had special knowledge not available to Plaintiff or his doctors, and as to which they made affirmative representations in violation of all applicable laws, and concealed material facts relating to the defective nature and risks of Levaquin, which were peculiarly within their knowledge, knowing that Plaintiff and his doctors would rely on the presumption that no such facts exist.

140. Defendants knew that Levaquin can cause severe and permanent injuries, including, without limitation, tendon ruptures; indeed, Defendants knew that tendon injuries associated with Levaquin had occurred for years. Defendants had actual knowledge at the time of sale of Levaquin to the Plaintiff that Levaquin created a risk of serious bodily injury to its users, including, without limitation, tendon injuries, based, in part, upon test results, studies, adverse reaction reports, regulatory action in foreign countries, published reports, and their own clinical trials and post-marketing surveillance of Levaquin and its molecularly similar counterpart, ofloxacin.

141. At all times during the course of dealing between Defendants and Plaintiff, Defendants knowingly and recklessly omitted and concealed information peculiarly within their knowledge to the Plaintiff, his doctors, the scientific community and to the general public – *e.g.*, the dangers of Levaquin, including the special risk of tendon injury and tendon ruptures, particularly to the elderly – knowing that the scientific community, the general public, the Plaintiff, and his doctors, would rely on the presumption that the dangers did not exist.

142. Defendants actively concealed from the Plaintiff, his doctors, the scientific community and the general public:

HUTTON
& HUTTON
Law Firm, L.L.C.

Tallgrass Exec. Park
8100 E. 22nd St. N.
Building 1200
Wichita, Kansas
67226-2312

Mailing Address:
P.O. Box 638
Wichita, Kansas
67201-0638

316.688.1166
316.686.1077 (*fax*)
www.huttonlaw.com

a. that their own results, published studies, and/or clinical trials showed a statistically high risk of serious tendon injuries associated with Levaquin including, without limitation, tendon ruptures; and/or;

b. that Levaquin was not adequately tested for serious tendon injuries before or after its introduction on the market; and/or

c. that Levaquin was, in fact, unsafe as it posed a risk of injury that outweighed any purported benefits.

143. Defendants misrepresented that Levaquin was safe and effective for its intended uses by affirmative misrepresentation and/or active concealment and omission of material facts regarding the safety and effectiveness of Levaquin; and, by their course of conscious or intentional conduct succeeded in selling and marketing dangerous, defective, and ineffective antibiotics to Plaintiff. Defendants intentionally omitted, concealed, and/or suppressed this information from consumers, including Plaintiff and his doctors, in order to avoid losses in sales to consumers and market share to its major competitors.

144. Moreover, Defendants engaged in an aggressive marketing strategy, which included false representations regarding the safety profile and known adverse side effects of Levaquin to create the impression and to convey to Plaintiff and the general public that:

a. Levaquin had a favorable safety profile and was fit for human consumption;

b. the benefits of taking Levaquin outweighed any associated risks; and

c. the use of Levaquin was safe and had fewer adverse health and side effects than Defendants knew or should have known at the time of these representations.

145. The omissions, misrepresentations, and concealment described above occurred, without limitation, in the Levaquin warning labels, advertisements and promotional materials, in the

HUTTON & HUTTON Law Firm, L.L.C.

Tallgrass Exec. Park
8100 E. 22nd St. N.
Building 1200
Wichita, Kansas
67226-2312

Mailing Address:
P.O. Box 638
Wichita, Kansas
67201-0638

316.688.1166
316.686.1077 (*fax*)
www.huttonlaw.com

Johnson & Johnson funded or created scientific reports, and the failure to provide other special notification of the dangers of Levaquin to the Plaintiff or his physicians, for example, "Dear Doctor" letters. The Defendants' statements omitted, concealed, and misrepresented the dangers of serious injury, including, but not limited to, tendon ruptures, particularly to the elderly, to Plaintiff and his prescribing doctors.

146. Defendants engaged in fraud by deliberately and affirmatively concealing and failing to disclose adverse reactions of Levaquin to Plaintiff, his doctors, the scientific community, and the general public, and by disseminating only positive and misleading scientific data, and by concealing scientific data that showed increased risk of tendon-related injury.

147. Plaintiff Mendell Butler, and his prescribing physicians, relied on the warning labels as they appeared in the patient package insert at the time they prescribed and consumed Levaquin respectively. The applicable warnings concealed and omitted material facts relating to the defective nature and risks of Levaquin. These dangers were peculiarly within the Defendants' knowledge, and were omitted and concealed knowing that Plaintiff and his doctors would rely on the presumption that no such facts exist.

148. Defendants knew or should have known that their representations and omissions regarding the safety of Levaquin were, in fact, false and/or misleading, and actively made such representations and omissions with the intent, design, and purpose that Plaintiff and others, including prescribing physicians, rely on these representations leading to the prescription, purchase and consumption of Levaquin.

149. At all times herein, Plaintiff and his physicians were unaware of the dangers of Levaquin with respect to tendon ruptures, including the special risk of tendon injury to the elderly, and were reasonably misled by the Defendants' omission of information about this danger.

HUTTON
& HUTTON
Law Firm, L.L.C.

Tallgrass Exec. Park
8100 E. 22nd St. N.
Building 1200
Wichita, Kansas
67226-2312

Mailing Address:
P.O. Box 638
Wichita, Kansas
67201-0638

316.688.1166
316.686.1077 (*fax*)
www.huttonlaw.com

150. At all times herein, Plaintiff and his physicians were unaware of the falsity underlying Defendants' statements and reasonably believed Defendants' false statements about the safety and efficacy of Levaquin to be true.

151. Plaintiff and his doctors could not have discovered Defendants' fraudulent and misleading conduct at an earlier date through the exercise of reasonable diligence because Defendants actively concealed their deceptive, misleading and unlawful activities.

152. Plaintiff and his physicians did, and could be expected to rely, reasonably and justifiably, on Defendants' representations and omissions because Defendants held themselves out as having expertise and specialized knowledge in the pharmaceutical industry.

153. To his detriment, Plaintiff justifiably relied upon, and/or was induced by, Defendants' false statements and active concealment over the safety of Levaquin, in part, because at no time did Plaintiff or his physicians have the knowledge or expertise necessary to independently evaluate the safety of Levaquin.

154. Defendants willfully, wantonly, uniformly, deliberately, or recklessly misrepresented, concealed, suppressed, and omitted material facts about the safety and efficacy of Levaquin in order to induce Plaintiff to purchase Levaquin; Plaintiff and his physicians did rely, reasonably and justifiably, upon Defendants' material misrepresentations and omissions about Levaquin when agreeing to purchase and/or ingest Levaquin.

155. As a direct and proximate result of Defendants' false representations and/or active concealment of material facts regarding the safety and efficacy of Levaquin, Plaintiff ingested Levaquin and suffered severe and debilitating injuries and economic loss, including but not limited to, cost of medical care, rehabilitation, and pain and suffering in an amount to be proven at trial.

HUTTON
& HUTTON
Law Firm, L.L.C.

Tallgrass Exec. Park
8100 E. 22nd St. N.
Building 1200
Wichita, Kansas
67226-2312

Mailing Address:
P.O. Box 638
Wichita, Kansas
67201-0638

316.688.1166
316.686.1077 (*fax*)
www.huttonlaw.com

SIXTH CAUSE OF ACTION
VIOLATION OF KANSAS CONSUMER PROTECTION ACT ("KCPA")
(Deceptive and Unconscionable Acts or Practices)
(K.S.A. 50-623, *et seq.*)

156. Plaintiff incorporates here all prior paragraphs of this Complaint and further alleges:

157. Plaintiff was and is a consumer per K.S.A §50-624(b) and purchased Levaquin for his personal consumption.

158. Defendants were and are suppliers of Levaquin per K.S.A. §50-624(j).

159. Defendants represented that Levaquin had characteristics, namely that it was safe when used as intended, that Defendants knew, or had reason to know, did not exist.

160. Defendants willfully concealed, suppressed, omitted, and/or failed to state the material facts of the unsafe nature of Levaquin and otherwise committed deceptive and unconscionable acts as set out in K.S.A. §50-626 and -627.

161. Plaintiff, his health care providers and pharmacies/pharmacists reasonably relied on Defendants' representations and/or its concealment, suppression, omission, and/or failure to state the material facts regarding the unsafe nature of Levaquin.

162. Defendants' representations and/or their concealment, suppression, omission, or failure to state material facts, are a direct and proximate cause of, or contributed to, the Plaintiff's irreparable injuries and damages, including economic and noneconomic damages that Plaintiff has suffered and will continue to suffer.

163. The remedies under the KCPA entitle Plaintiff to recover for his injuries and damages and, should the record so support, Kansas law entitles him to seek punitive damages.

HUTTON
& HUTTON
Law Firm, L.L.C.

Tallgrass Exec. Park
8100 E. 22nd St. N.
Building 1200
Wichita, Kansas
67226-2312

Mailing Address:
P.O. Box 638
Wichita, Kansas
67201-0638

316.688.1166
316.686.1077 (*fax*)
www.huttonlaw.com

SEVENTH CAUSE OF ACTION
UNJUST ENRICHMENT

164. Plaintiff incorporates here all prior paragraphs of this Complaint and further alleges:

165. As the intended and expected result of their conscious wrongdoing, Defendants have profited and benefited from Plaintiff's purchase and consumption of Levaquin.

166. Defendants voluntarily have accepted and retained those profits and benefits, derived from Plaintiff, with full knowledge and awareness that, as a result of Defendant's fraud and other conscious and intentional wrongdoing, Plaintiff did not receive a product of the quality, nature, or fitness that Defendants had, or that Plaintiff, as a reasonable consumer, expected to receive.

167. By virtue of the conscious wrongdoing alleged above, Defendants have been unjustly enriched at the expense of Plaintiff, who is entitled in equity, and hereby seeks, the disgorgement and restitution of Defendants' wrongful profits, revenues, and benefits, to the extent and in the amount that the Court deems appropriate, and such other relief as the Court deems just and proper to remedy Defendants' unjust enrichment.

PRAYER

WHEREFORE, Plaintiff prays for relief against Defendants as follows:

a. Compensatory damages according to proof, in excess of the amount required for federal diversity jurisdiction, and in an amount to compensate Plaintiff fully for all of his injuries and damages, both past and present;

b. Special damages according to proof, in excess of the amount required for federal diversity jurisdiction and in an amount to compensate Plaintiff fully for all of his injuries and damages, both past and present, including but not limited to, past and

HUTTON
& HUTTON
Law Firm, L.L.C.

Tallgrass Exec. Park
8100 E. 22nd St. N.
Building 1200
Wichita, Kansas
67226-2312

Mailing Address:
P.O. Box 638
Wichita, Kansas
67201-0638

316.688.1166
316.686.1077 (*fax*)
www.huttonlaw.com

future medical expenses, costs for past and future rehabilitation and/or home health care, and pain and suffering;

c. Double or triple damages as allowed by law;

d. Punitive damages as allowed by law and in an amount to be determined at trial;

e. Disgorgement of profits;

f. A full refund for all prescriptions paid;

g. Attorneys' fees, expenses, and costs of this action;

h. Pre-judgment and post-judgment interest in the maximum amount allowed by law; and

i. Such further relief as the Court deems necessary, just, and proper.

Dated: 26 March 2010

Respectfully submitted,

/s/ Deborah B. McIlhenny

Deborah B. McIlhenny, KS #18721
Mark B. Hutton, KS # 10112
Andrew W. Hutton, KS #10264
HUTTON & HUTTON LAW FIRM, L.L.C.
8100 East 22nd Street North, Building 1200
Wichita, KS 67226
Telephone: 316.688.1166/686.1077 (fax)
www.huttonlaw.com

HUTTON
& HUTTON
Law Firm, L.L.C.

Tallgrass Exec. Park
8100 E. 22nd St. N.
Building 1200
Wichita, Kansas
67226-2312

Mailing Address:
P.O. Box 638
Wichita, Kansas
67201-0638

316.688.1166
316.686.1077 (*fax*)
www.huttonlaw.com